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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,874	06/07/2000	ERICH WANKER	V0179/7000	6909

7590 07/29/2003

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/29/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,874	WANKER ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 12-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1/31/00</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim status

1. Claims 6, 8-11, 13-14, 16 and 18 have been amended and claims 20-21 have been cancelled, as requested in amendment of Paper No. 10, filed on November 25, 2002.

Claims 1-19 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that "the fusion protein includes both elements aa and ab" (see last paragraph of page 3 of Paper No. 10. The following communication from the office of Paper No. 11 provided explanation of the restriction requirement, and the election of a single molecular embodiment of a fusion protein, such as GST as (aa) and huntingtin as (ab) polypeptides, was made in Paper No. 12, filed on February 13, 2003. Thus, the requirement for restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-6 and 8-11 correspond to elected species of Group I.

Claims 7 and 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claims 1-6 and 8-11, in so far as they are drawn to a nucleic acid molecule encoding a fusion GST/huntingtin protein, a protein encoded thereby, a vector and a host transformed with the vector, are under examination in the instant office action.

Sequence compliance

4. The text on pages 30 and 31 of the instant specification is not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The appropriate format for sequence identifiers is SEQ ID NO:X, wherein "X" is the sequence number. Appropriate correction is required.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Appropriate action is required.

Drawings

6. The drawings filed on 6/7/2000 are acceptable subject to correction of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

7. Furthermore, Figures 10 and 11 of the instant application are presented on separate pages or in separate panels. 37 C.F.R. § 1.84(u) (1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. For example, the two panels of Figure 10 in the instant specification should be renumbered "Figure 10A" – "Figure 10B" rather than

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"Figure 10". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, Figure 10 is divided into Figures 10A-10B, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 5 are directed to a functional derivative of a fusion protein or huntingtin protein and claims 8 is directed to a functional fragment or derivative of GST. Claims 2-4, 6 and 9-11 are dependent claims. However, the instant specification fails to describe the entire genus of proteins which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a fusion protein comprising

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GST and huntingtin. The subject matter, which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are proteins, which are functional derivatives of a fusion protein comprising GST and huntingtin or functional fragments or derivatives of GST. First, the claims are not limited to a protein with a specific amino acid sequence. The claims only require the polypeptide share some degree of structural similarity to the fusion protein comprising GST and huntingtin or to GST. The specification only describes one molecular embodiment, which is a fusion protein comprising GST and huntingtin or GST itself and fails to teach or describe any other molecular embodiments which lack the structure of a fusion protein comprising GST and huntingtin or GST itself and have the functions possessed by the recited protein. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the fusion protein comprising GST and huntingtin and also GST itself. The specification does not provide a complete structure of those functional derivatives of a fusion protein comprising GST and

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huntingtin or functional fragments or derivatives of GST. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those functional derivatives of a fusion protein comprising GST and huntingtin or functional fragments or derivatives of GST) because the specification teaches only the one embodiment of the fusion protein comprising GST and huntingtin. Therefore, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 5 is vague and indefinite in so far as it employs the term "huntingtin" as a limitation. This term appears to encompass a plurality of different molecular embodiments, as evidenced by the text on page 2, first paragraph of the instant specification, for example, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "huntingtin". Moreover, because the instant

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specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "huntingtin", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

11. Claim 11 recites the limitation "a transgenic animal or a transgenic plant" as "a host" in claim 1. There is insufficient antecedent basis for this limitation in the claim because claim 1 recites "a host transformed with the vector", which implies that "a host" is a host cell, not an animal or a plant because it is not clear how to transform an animal or a plant with a vector.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Onodera et al. (FEBS Letters, 1996, 399, pp.135-9).

Claims 1-4, 6 and 8-11 are directed to a composition comprising a nucleic acid encoding a fusion protein comprising a GST and an amyloidogenic polypeptide further comprising a polyglutamine expansion, an expression vector and a host cell transformed with the said vector. Onodera et al. disclose cDNA encoding polyglutamine repeat-GST fusion proteins, plasmids and cell cultures containing the indicated plasmids. The fusion proteins of Onodera et al. contained polyglutamine expansion of 14 to 79 uninterrupted glutamines (see section Materials and methods

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on page 135-136 of the publication). As evidenced by publication of Perutz (1996, reference of IDS submitted on January 31, 2000), “[p]oly-L-glutamines form pleated sheets of β -strands held together by hydrogen bonds” (see the abstract). In the absence of clear definition of “an amyloidogenic (poly)peptide” presented in the instant specification, one skilled in the art would reasonably consider DRPLA proteins containing polyglutamine expansions of Onodera et al. “an amyloidogenic polypeptides” because these proteins would form β -sheets aggregates due to the presence of polyglutamins. Thus the publication of Onodera et al. meets the limitations of claims 1-4, 6 and 8-11.

Furthermore, Applicant is advised that “a fragment” of huntingtin, recited in claim 5, encompasses a fragment as little as one amino acid. Thus, DRPLA proteins of Onodera et al. comprise “a fragment” of huntingtin protein of instant claim 5, and, consequently, Onodera et al. anticipate claim 5 of the instant invention.

Double Patenting

13. Applicant is advised that should claim 1 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

14. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

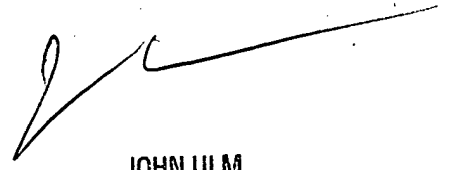
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Olga N. Chernyshev, Ph.D.
July 25, 2003

OC

A handwritten signature in black ink, appearing to read 'J. ULM', with a long horizontal stroke extending to the right.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800